



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0709]

#### Prescription Drug User Fee Rates for Fiscal Year 2022; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice entitled “Prescription Drug User Fee Rates for Fiscal Year 2022” that appeared in the *Federal Register* of August 16, 2021. The document announced the Fiscal Year 2022 fee rates for the Prescription Drug User Fee Act. The document published with errors. The errors did not have an impact on the previously published user fee rates but are corrected in this document for clarity.

**FOR FURTHER INFORMATION CONTACT:** Misbah Tareen, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077A, Beltsville, MD 20705-4304, 301-796-3997.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of August 16, 2021 (86 FR 45732), appearing on page 45736 in FR Doc. 2021-17505, the following corrections are made:

1. In the second column, in the last sentence of the third paragraph under “D. FY 2022 Statutory Fee Revenue Adjustments for Operating Reserve”, “both user fee funds available for obligation \$126,873,636 and funds that are considered unavailable due to a lack of appropriations \$98,850,995” is corrected to read “user fee funds considered unavailable due to a lack of appropriations \$78,850,995, additional fee funds that are available for obligation but set aside for future year refunds as a matter of prudent operations \$20,000,000, and carryover net of unavailable funds and the set-aside \$126,873,636.”

2. The fourth footnote is corrected by removing the text and replacing it with: “In recent PDUFA Annual Financial Reports, the category “unavailable for use” has been used to

refer both to (1) fee funds that are considered unappropriated and (2) appropriated fee funds the Agency has maintained to provide for any refunds. FDA intends to discontinue use of the category “unavailable for use” in forthcoming reports to better reflect the difference between these line items and improve the clarity of its reporting. Although certain amounts have been maintained for future refunds as a matter of prudent operations, these amounts are considered appropriated and are available for obligation.”

3. In the second column, in the fifth paragraph under “D. FY 2022, Statutory Fee Revenue Adjustments for Operating Reserve”, sentences 4 through 7 are corrected by removing the text and replacing it with “FDA has decided to make an available operating reserve adjustment that is intended to increase the amount of available funds to approximately 8 weeks by the end of FY 2022, representing the low end of the 8- to 10-week range while mitigating the impact on fee amounts. FDA estimates the cost of operations per week is \$22,144,672. Before the operating adjustment, the estimated end of year FY 2022 available operating reserve is \$145,677,240, which equates to about 6½ weeks of available operating reserves. Adding the FY 2022 operating reserve adjustment of \$39,402,923 to this amount is expected to provide approximately 8 weeks of available operating reserve, or \$185,080,162 (including \$20,000,000 in available fee funds maintained for any future refunds), and a total carryover of operating reserves (including unavailable funds) of \$263,931,157.”

Dated: March 21, 2022.

**Andi Lipstein Fristedt,**

*Deputy Commissioner for Policy, Legislation, and International Affairs,  
U.S. Food and Drug Administration.*

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